

**REMARKS**


Consideration of the above-identified application in view of the preceding amendments and following remarks is respectfully requested. Claims 33-65 are pending in this application. By this Amendment, Applicants have cancelled Claims 1-32 without prejudice and added new Claims 33-65. Informalities in the specification have also been corrected by submitting a substitute specification herewith. It is respectfully submitted that no new matter has been introduced by these amendments, as support therefor is found throughout the specification and drawings.

In accordance with 37 C.F.R. 1.125, a clean version and a marked up version of the substitute specification are attached hereto. Any additional fees or overpayments due as a result of filing the present papers may be applied to Deposit Account No. 04-1105. It is respectfully submitted that all of the claims now remaining in this application, namely Claims 33-65, are in condition for allowance, and such action is earnestly solicited.

If after reviewing this amendment, the Examiner believes that a telephone interview would facilitate the resolution of any remaining matters the undersigned attorney may be contacted at the number set forth herein below.

Respectfully submitted,

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## Psoriasis Formulation and Method of Preparation

### CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims priority to United Kingdom Patent Application No. 0217372.2, filed July 25, 2002, which is the basis for International Patent Application No. GB2003/003257, filed July 18, 2003, each of which is incorporated herein by reference.

### BACKGROUND OF THE INVENTION

#### 1. Field of the Invention

[0002] This invention relates to formulations which can be used in the treatment of dermatological disorders, such as psoriasis. The current invention also relates to a method of preparation that is more acceptable for use than many current treatments.

#### 2. Background of the Related Art

[0003] The term dermatological disorders covers a wide range of disorders, such as psoriasis and eczema. These disorders affect a large number of people. Psoriasis is a chronic recurring skin disease, the scope

of which can vary considerably from mild outbreaks, to severe cases.

[0004] The underlying problem of psoriasis is currently thought to be that new skin cells are produced too quickly, so that the old skin cells have not had time to die off and be removed. The resulting overproduction of skin cells is red and raised patches on the skin.

[0005] Various treatments have been suggested for psoriasis. In particular, many sufferers find that coal tar has a particularly beneficial effect and improves many of the symptoms of psoriasis. Unfortunately, although coal tar has been found to be effective against the symptoms of psoriasis in many patients, as a substance coal tar is not the most user friendly. Coal tar has a very pungent smell and has a black colour which stains both clothing and bed linen. This can be very off-putting for many psoriasis sufferers and is generally inconvenient for regular use.

[0006] It can therefore be seen that it would be beneficial to provide a psoriasis treatment which contains coal tar, but which is formulated in a manner which is appropriate for regular use.

#### SUMMARY OF THE INVENTION

[0007] It is an object of the present invention to provide a psoriasis treatment which comprises coal tar.

[0008] A further object of the present invention is to provide a psoriasis treatment in a formulation which does not stain clothes and is not unpleasant smelling.

[0009] A yet further object of the present invention is to provide a psoriasis treatment in a formulation that can be easily applied.

[0010] According to a first aspect of the present invention, there is provided a method of preparing a composition for the treatment of dermatological disorders, wherein coal tar is filtered to remove impurities by filter compression.

[0011] Preferably zinc pyrithione is incorporated into the composition.

[0012] Preferably the coal tar is filtered by being fed through a compressed charcoal filter.

[0013] Most preferably the coal tar is fed through the filter at 17 to 19 psi.

[0014] Most preferably the coal tar is fed through the filter at 18 psi.

[0015] Preferably compressed air is used to force the coal tar through the filter.

[0016] Preferably the coal tar is left in the filter system for 8 hours.

[0017] Preferably the fluid that has been passed through the filter is boiled.

[0018] Most preferably the fluid is boiled for 5 minutes.

[0019] Preferably the boiled, filtered fluid is allowed to cool to room temperature.

[0020] Most preferably the top layer of the boiled, filtered fluid is refiltered.

[0021] Optionally, refiltering is through a nylon mesh.

[0022] Preferably a surfactant is added to the formulation.

[0023] Preferably the surfactant is an ionic surfactant.

[0024] Most preferably the surfactant is sodium lauryl sulphate.

[0025] Preferably a carrier is added to the formulation.

[0026] Most preferably multiple carriers are added to the formulation.

[0027] Optionally a carrier may be isopropyl myristate.

[0028] A further option is that a carrier may be ethyl alcohol.

[0029] Preferably the formulation is placed in a spray or aerosol container.

[0030] Preferably a mild steroid is added to the formulation.

[0031] Preferably the mild steroid is 0.05% dipropionate.

[0032] According to a second aspect of the present invention, there is provided a composition for the treatment of dermatological disorders, comprising:

☐ coal tar;  
☐ zinc pyrithione;  
☐ one or more surfactants; and  
☐ one or more carriers.

[0033] Preferably the dermatological disorder is psoriasis.

[0034] Preferably the composition also contains allantoin.

[0035] Preferably the surfactant is an ionic surfactant.

[0036] Most preferably the surfactant is sodium lauryl sulphate.

[0037] Optionally a carrier may be isopropyl myristate.

[0038] A further option is that a carrier may be ethyl alcohol.

[0039] Preferably the composition will also comprise an anti-fungal agent.

[0040] Preferably the anti-fungal agent is undecylenic acid.

[0041] Preferably the composition formulation comprises the following ingredients:

☐ zinc pyrithione;  
☐ alcoholic extract of coal tar;  
☐ allantoin;  
☐ sodium lauryl sulphate;  
☐ isopropyl myristate;  
☐ ethyl alcohol; and  
☐ undecylenic acid.

[0042] Optionally the composition formulation comprises a mild steroid.

[0043] Preferably the mild steroid is dipropionate.

[0044] Preferably the mild steroid is 0.05%  
dipropionate.

[0045] Preferably the composition comprises the  
following ingredients in the following amounts:

<input type="checkbox"/> zinc pyrithione	_____	_____ 0.20%
<input type="checkbox"/> alcoholic extract of coal tar	_____	_____
_____ 0.25%		
<input type="checkbox"/> allantoin	_____	_____
_____ 0.25%		
<input type="checkbox"/> sodium lauryl sulphate	_____	_____ 0.10%
<input type="checkbox"/> isopropyl myristate	_____	_____
<input type="checkbox"/> ethyl 19a, 15 $\beta$ -chol	_____	_____ 49.45%
<input type="checkbox"/> undecylenic acid	_____	_____ 0.30%

[0046] Preferably the composition is provided in a  
spray form.

[0047] Alternatively, the composition is provided in  
an aerosol form.

#### BRIEF DESCRIPTION OF THE FIGURE

[0048] In order to provide a better understanding of  
the present invention, embodiments will now be described  
by way of example only, and with reference to the  
following Figure:

[0049] Figure 1 shows a charcoal filter system for  
use according to the first aspect of the present  
invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0050] Coal tar, when untreated, has a very pungent smell and is black in colour. The black colouring will stain clothing and bed linen on contact.

[0051] In order to produce an acceptable formulation for use in treating psoriasis or other dermatological disorders, coal tar is filtered in order to eradicate the smell and remove many of the impurities which result in staining.

[0052] Referring to Figure 1, in the preferred embodiment, crude coal tar is mixed with 2% alcohol (which acts as a thinner and is poured into a charcoal filter system 1 via the coal tar input 2. Clean, compressed air is then applied via the air input 3 at 18 psi (which can be varied between 17 to 19 psi).

[0053] The charcoal filter system 1 comprises a fine mesh gauze filter 4 and a charcoal filter 5 which the coal tar mixture is pushed through into the catch tank 6. It is worth noting that too much pressure forces charcoal through the system and too little does not push the coal tar mixture through.

[0054] The system 1 is left in place overnight with the compressed air still in place. In the preferred embodiment, the system is left for approximately 8 hours. The filtered fluid is then taken from the catch tank 6 via the exit flow tap 7 and is boiled (in the preferred embodiment it is boiled for 5 minutes) and left to completely cool to room temperature. The fluid now has a

scum on top which is filtered through a nylon mesh to give a clear, completely odourless liquid which does not stain materials.

[0055] A surfactant and a carrier is then added to make the formulation completely soluble. In the preferred embodiment, the surfactant is an ionic surfactant, sodium lauryl sulphate. Multiple carriers are used, and in the preferred embodiment, these are isopropyl myristate and ethyl alcohol. Zinc pyrithione is also added to the formulation, which increases the effectiveness of the formulation to a previously unexpected degree. Allantoin is also added to the formulation.

[0056] In the preferred embodiment, an anti-fungal agent is also added to the formulation. This anti-fungal agent is undecylenic acid in the preferred embodiment.

[0057] While the invention has been described with respect to preferred embodiments, those skilled in the art will readily appreciate that various changes and/or modifications can be made to the invention without departing from the spirit or scope of the invention as defined by the appended claims.

1    CLAIMS

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3    1.    A method of preparing a composition for the  
4           treatment of dermatological disorders, wherein coal  
5           tar is filtered to remove impurities by filter  
6           compression.

7

8    2.    A method as in Claim, wherein zinc pyrithione is  
9           incorporated into the composition.

10

11   3.    A method as in any of the previous Claims, wherein  
12           the coal tar is filtered by being fed through a  
13           compressed charcoal filter.

14

15   4.    A method as in Claim 3, wherein the coal tar is fed  
16           through the filter at 17 to 19 psi.

17

18   5.    A method as in Claim 3, wherein the coal tar is fed  
19           through the filter at 18 psi.

20

21   6.    A method as in Claims 3 to 5, wherein compressed air  
22           is used to force the coal tar through the filter.

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24   7.    A method as in Claims 3 to 6, wherein the coal tar  
25           is left in the filter system for 8 hours.

26

27   8.    A method as in Claims 3 to 7, wherein the fluid that  
28           has been passed through the filter is boiled.

29

30   9.    A method as in Claim 8, wherein the fluid that has  
31           been passed through the filter is boiled for 5  
32           minutes.

33

- 1 10. A method as in Claims 8 or 9, wherein the boiled,  
2 filtered fluid is allowed to cool to room  
3 temperature.  
4
- 5 11. A method as in Claims 8, 9 or 10, wherein the top  
6 layer of the boiled, filtered fluid is refiltered.  
7
- 8 12. A method as in Claim 11, wherein refiltering is  
9 through a nylon mesh.  
10
- 11 13. A method as in any of the previous Claims, where a  
12 surfactant is added to the formulation.  
13
- 14 14. A method as in Claim 13, wherein the surfactant is  
15 an ionic surfactant.  
16
- 17 15. A method as in Claims 13 or 14, wherein the  
18 surfactant is sodium lauryl sulphate.  
19
- 20 16. A method as in any of the previous Claims, wherein a  
21 carrier is added to the formulation.  
22
- 23 17. A method as in any of the previous Claims, wherein  
24 multiple carriers are added to the formulation.  
25
- 26 18. A method as in Claims 16 or 17, wherein the carrier  
27 is isopropyl myristate.  
28
- 29 19. A method as in Claims 16 or 17, wherein the carrier  
30 is ethyl alcohol.  
31

1 20. A method as in any of the previous Claims, wherein  
2 the formulation is placed in a spray or aerosol  
3 container.  
4

5 21. A composition for the treatment of dermatological  
6 disorders comprising:  
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- 8 • coal tar;
- 9 • zinc pyrithione;
- 10 • one or more surfactants; and
- 11 • one or more carriers

12

13 22. A method as in Claim 21, wherein the composition  
14 also contains allantoin.  
15

16 23. A composition as in Claims 21 and 22, wherein the  
17 surfactant is an ionic surfactant.  
18

19 24. A composition as in Claims 21 to 23, wherein the  
20 surfactant is sodium lauryl sulphate.  
21

22 25. A composition as in Claims 21 to 24, wherein the  
23 carrier is isopropyl myristate.  
24

25 26. A composition as in Claims 21 to 24, wherein the  
26 carrier is ethyl alcohol.  
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28 27. A composition as in Claims 21 to 25, wherein the  
29 composition also comprises an anti-fungal agent.  
30

31 28. A composition as in Claim 27, wherein the anti-  
32 fungal agent is undecylenic acid.  
33

1 29. A composition for the treatment of dermatological  
2 disorders, comprising:

3

- 4 • zinc pyrithione;
- 5 • alcoholic extract of coal tar;
- 6 • allantoin;
- 7 • sodium lauryl sulphate;
- 8 • isopropyl myristate;
- 9 • ethyl alcohol; and
- 10 • undecylenic acid

11

12 30. A composition as in Claim 29, wherein the  
13 ingredients in the following amounts:

14

- |                                    |        |
|------------------------------------|--------|
| 15 • zinc pyrithione               | 0.20%  |
| 16 • alcoholic extract of coal tar | 0.25%  |
| 17 • allantoin                     | 0.25%  |
| 18 • sodium lauryl sulphate        | 0.10%  |
| 19 • isopropyl myristate           | 49.45% |
| 20 • ethyl alcohol                 | 49.45% |
| 21 • undecylenic acid              | 0.30%  |

22

23 31. A composition as in Claims 21 to 30, wherein the  
24 composition is provided in a spray form.

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26 32. A composition as in Claims 21 to 30, wherein the  
27 composition is provided in an aerosol form.

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PATENT

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RED-LINE SUBSTITUTE SPECIFICATION

**ABSTRACT**

Psoriasis formulation and method of preparation

The invention relates to Fformulations which can be used in the treatment of dermatological disorders, in particular psoriasipsoriasis and s. The invention also relates to a methods of preparation of said formulations that is more acceptable for use and produces a more user friendly composition utilizing coal tar.